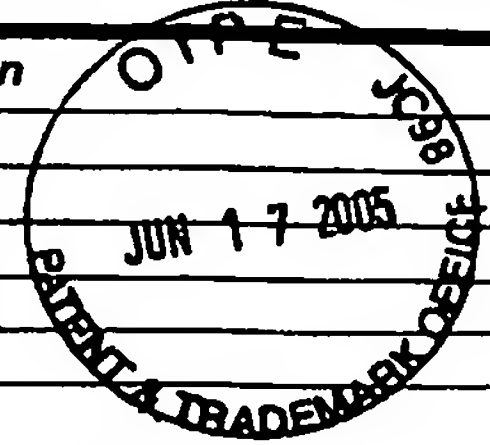


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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: June 17, 2005 (use as many sheets as necessary)				Application Number	10/025,967
				Filing Date	12/26/2001
				First Named Inventor	Shigeru Kamei
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	1	of	5	Attorney Docket Number	074129-0510



U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
DR	A1	1,995,970		DOROUGH	03/35	
	A2	2,362,511		TEETERS	11/44	
	A3	2,438,208		FLLACHIONE et al.	03/48	
	A4	2,703,316		SCHNEIDER et al.	03/55	
	A5	2,758,987		SAIZBERG	08/56	
	A6	3,043,782		JENSEN	07/62	
	A7	3,092,553		FISHER et al.	06/63	
	A8	3,297,033		SCHMITT et al.	01/67	
	A9	3,523,906		VRANCKEN et al.	08/70	
	A10	3,539,465		HIESTAND et al.	11/70	
	A11	3,565,869		DePROSPERO	02/71	
	A12	3,636,956		SCHNEIDER	01/72	
	A13	3,645,911		van BESAUW et al.	02/72	
	A14	3,691,090		KITAJIMA et al.	09/72	
DR	A15	3,755,553		SCRIBNER et al.	08/73	
	A16	3,755,558		SCRIBNER	08/73	
	A17	3,839,297		WASSERMAN et al.	10/75	
	A18	3,882,228		BONCEY	05/75	
	A19	3,890,283		CASEY et al.	06/75	
	A20	3,912,692		CASEY et al.	10/75	
	A21	3,922,338		ESTEVENEL et al.	11/75	
	A22	3,956,172		SAEKI et al.	05/76	
	A23	4,137,921		OKUZUMI et al.	02/79	
	A24	4,234,571		NESTOR et al.	11/80	
	A25	4,249,531		HELLER et al.	02/81	
	A26	4,272,398		JAFFE	06/81	
	A27	4,273,920		NEVIN	06/81	
DR	A28	4,384,975		FONG	05/83	
	A29	4,389,330		TICE et al.	06/83	
	A30	4,479,911		FONG	10/84	
	A31	4,555,399		HSIAO	11/85	
	A32	4,605,730		SHALABY et al.	08/86	
	A33	4,622,244		LAPKA et al.	11/86	
	A34	4,637,905		GARDNER	01/87	
	A35	4,652,441		OKADA et al.	03/87	
	A36	4,667,191		TANAKA et al.	06/87	
	A37	4,710,384		ROTMAN	12/87	
DR	A38	4,728,721		YAMAMOTO et al.	03/88	
	A39	4,849,228		YAMAMOTO et al.	07/89	

Examiner
Signature

David Linton

Date
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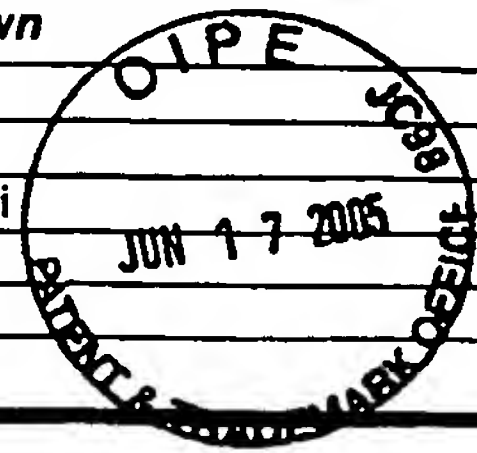
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				Filing Date	12/26/2001
				First Named Inventor	Shigeru Kamei
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	074129-0510
Sheet	2	of	5		



U.S. PATENT DOCUMENTS					
	U.S. Patent Document	U.S. Patent Document	U.S. Patent Document	U.S. Patent Document	U.S. Patent Document
X	A40	4,917,893		OKADA et al.	04/90
X	A41	4,954,298		YAMAMOTO et al.	09/90
X	A42	5,330,767		YAMAMOTO et al.	07/94
X	A43	5,480,656		OKADA et al.	01/96
X	A44	5,575,987		KAMEI et al.	11/96
X	A45	5,631,020		OKADA et al.	05/97
X	A46	5,643,607		OKADA et al.	07/97
X	A47	5,716,640		KAMEI et al.	02/98
X	A48	5,972,891		KAMEI et al.	10/99
X	A49	6,528,093		KAMEI et al.	03/2003

FOREIGN PATENT DOCUMENTS								
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
X	A50	CA	1 169 090		IMPERIAL CHEMICAL INDUSTRIES PLC	02/1982		
X	A51	EP	0 107 591	A2	UNITED STATES SURGICAL CORPORATION	05/1984		
X	A52	EP	0 145 240	A2	TAKEDA CHEMICAL INDUSTRIES LTD.	06/1985		
X	A53	EP	0 178 824	A1	TAKEDA CHEMICAL INDUSTRIES LTD.	04/1986		
X	A54	FR	2,551,072		SANDOZ-ERFINDUNGEN	08/1984		ABS.
X	A55	FR	2,126,270		DU PONT DE NEMOURS & CO.	02/1972		ABS.
X	A56	JP	40-500		FUJI PHOTO FILM CO. LTD.	01/1965	Eng. Translation of Detailed Description, Example 1 and Claim	PART.
X	A57	JP	43-3017		DASERU LTD.	02/1968	Eng. Translation of First Three Paragraphs and Claim 1	PART.
X	A58	JP	55-14193		HITACHI LTD.	05/1972		ABS.
X	A59	UK	1,351,409		SCRIBNER	02/72		
X	A60	UK	1,405, 108		DE JAEGER ET AL.	12/71		
X	A61	UK	2,145,422 A		SANDOZ LTD.	08/84		
X	A62	UK	2,246,514 A		SOCIETE DE CONSILIS DE RECHERCHES ET D' APPLICATIONS SCIENTIFIQUES	05/92		

Examiner Signature		Date Considered	3-24-06
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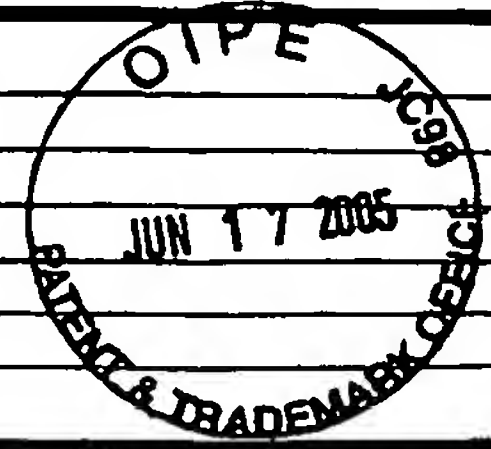
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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
X	A63	UK	929,402			11/59		
X	A64	WO	89/04673		BOARD OF REGENTS OF THE UNIV. OF TEXAS SYSTEM	06/89		
X	A65	WO	98/35654		OAKWOOD LABORATORIES LLC.	09/98		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
X	A66	ARSHADY, R., "Preparation of biodegradable microspheres and microcapsules: 2. Polyactides and related Polyesters," <u>Journal of Controlled Release</u> , Vol. 17, pp. 1-20, 1991	
X	A67	BAKAN, J. A. et al., "Microencapsulation," <u>The Theory and Practice of Industrial Pharmacy</u> , pp. 384-407, 1970	
X	A68	CHANG, T., "Biodegradable Semipermeable Microcapsules containing Enzymes, Hormones, Vaccines, and Other Biologicals," <u>Journal of Bioengineering</u> , 1:25-31, 1976	
X	A69	DRESSLER, et al., "Viable Prosthetic Interface," <u>J. Biomed. Mater. Res. Symposium</u> 1:169-178 (1971)	
X	A70	<u>Journal of the Chemical Society of Japan</u> , Industrial Chemistry Section, Volume 72, 1969 pp. 493-499 (English Translation of Sections 2.1 and 3.1)	
X	A71	<u>Journal of the Chemical Society of Japan</u> , Industrial Chemistry Section, 68(5), English Abstracts, A52-A53, pp. 983-986 (Japanese Text), 1965	
X	A72	KEIPERT, S. et al., "Antiglaumakotosahaltige Ophthalmika mit prolongierter Wirkung auf Basis makromolekularer Hilfsstoffe," <u>Die Pharmazie</u> , pp. 594-595 (English Abstract at page 594), August 1990	

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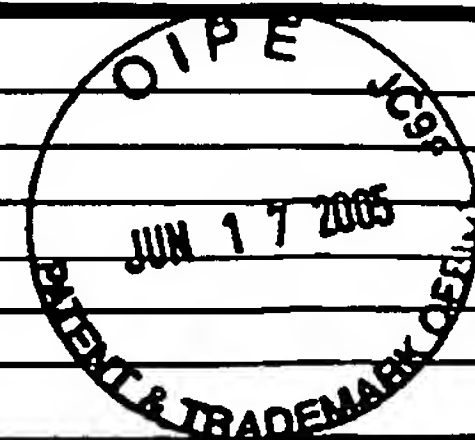
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				Examiner Name	Unassigned
Sheet	4	of	5	Attorney Docket Number	074129-0510



NON PATENT LITERATURE DOCUMENTS				
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X	A73	KONDO, A., <u>Microcapsule Processing and Technology</u> , Marcel Dekker, Inc., New York, New York (1979), Chapter I, "Microcapsules - General Concepts," pp. 1-10; Chapter III, "Applications and Studies of Microcapsules," pp. 18-26; Chapter IV, "History and Classification of Microencapsulation," pp. 27-34; Chapter X, "Microencapsulation Utilizing In-Liquid Drying Process (Complex Emulsion Method)," pp. 106-120		
X	A74	KULKARNI et al, "Biodegradable Poly(lactic acid) Polymers," <u>Journal of Biomedical Materials Research</u> , 5:169-181, 1971		
X	A75	KULKARNI et al, "Polyactic Acid for Surgical Implants," <u>Archives of Surgery</u> , 93(5):839-843, November 1966		
X	A76	LEWIS, D. et al., "Controlled Release of Bioactive Agents from Lactide/Glycolide Polymers," <u>Biodegradable Polymers as Drug Delivery Systems</u> , pp. 1-41, 1990		
X	A77	<u>Microcapsule</u> , Industrial Technology, Library 25, pages 102 (1971)		
X	A78	OGAWA, Y. et al, "Controlled Release of LHRH Agonist, Leuprolide Acetate, from Microcapsules: Serum Drug Level Profiles and Pharmacological Effects in Animals," <u>J. Pharma Pharmacol.</u> , PP. 439-444, 1989		
X	A79	OGAWA et al., "A new technique to efficiently entrap leuprolide acetate into microcapsules of polylactic acid or copoly (lactic/glycolic) acid," <u>Chem. Pharm. Bull.</u> , Vol. 36, No. 3, pp. 1095-1103, 1988.		
X	A80	OKADA, H. et al., "One- and three-month release injectable microspheres of the LH-RH superagonist leuporelin acetate," <u>Advanced Drug Delivery Reviews</u> , 28:43-70, 1997		
X	A81	OKADA, H. et al., "One-month release injectable microspheres of leuprolide acetate inhibit steroidogenesis and genital organ growth in rats," <u>International Journal of Pharmaceutics</u> , 54:231-239, 1989		
X	A82	OKADA, H. et al., <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> , 12(1):1-99, 1995		
X	A83	OMELCZUK, M. et al, "The Influence of Polymer Glass Transition Temperature and Molecular Weight on Drug Release from Tablets Containing Poly(DL-lactic Acid)," <u>Pharmaceutical Research</u> , Vol. 9, No. 1, pp. 26-32, January 1992		
X	A84	OMELCZUK, M. et al., "Effect of Thermal Treatment on the Physical-Mechanical and Dissolution Properties of Compacts Containing Biodegradable Polymers," <u>Proceedings of the Ninth International Pharmaceutical Technology Conference</u> , Veldhoven, the Netherlands, 1:28-44 (1990)		
X	A85	OMELCZUK, M. et al., "The Influence of Thermal Treatment on the Physical-Mechanical and Dissolution Properties of Tablets Containing Poly(DL-Lactic Acid)," <u>Pharmaceutical Research</u> 10(4):542-548 (1993)		

Examiner Signature	NOT CONSIDERED	Date Considered	
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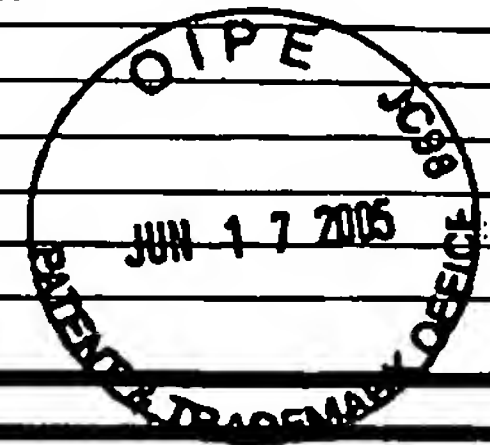
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X	A86	PITT, C. et al, "Sustained Drug Delivery Systems, 1. The Permeability of Poly(e-Caprolactone), Poly(DL-Lactic Acid), and Their Copolymers," <u>Journal of Biomedical Materials Research</u> , Vol. 13, pp. 418-507, 1979	
X	A87	SANDERS, L. et al, "Controlled Release of a Luteinizing Hormone-Releasing Hormone Analogue from Poly(d, l-lactide-co-glycolide)Microspheres," <u>Journal of Pharmaceutical Sciences</u> , Vol. 73, pp. 1294-1297, September 1994	
X	A88	SATO, T. et al, "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques," <u>Pharmaceutical Research</u> , Vol. 5, No. 1, pp. 21-30 January 1988	
X	A89	SCHMITT, E. et al., "Importance of Distinct Water Environments in the Hydrolysis of poly(DL-lactide-co-Glycolide)," <u>Macromolecules</u> , 27:743-748, 1994	
X	A90	Supplemental Information Disclosure Statement, YAMAMOTO et al, Serial No. 858,040 filed 11/3/87 with the U.S. Patent and Trademark Office	
X	A91	<u>The Pharmacopoeia of Japan</u> , Tenth Edition, pp. 16- 21, 1981	
X	A92	WANG, H.T. et al., "Influence of formulation methods on the in vitro controlled release of protein from poly (ester) microspheres," <u>Journal of Controlled Release</u> 17:23-31, 1991	
X	A93	WOO, B. H. et al, "Preparation, characterization and in vivo evaluation of 120-day poly(D,L-lactide) Leuprolide microspheres," <u>Journal of Controlled Release</u> , 75:307-315, 2001	

Not considered

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